

MASSACHUSETTS GENERAL HOSPITAL VINCENT OBSTETRIC AND GYNECOLOGY SERVICE

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Steven K. Galson, MD
Acting Director, Center for Drug Evaluation and Research
Phone (301) 594-5400 Fax (301) 594-6197

Dear Dr. Galson:

I strongly urge you to accept the application by Barr Laboratories to make Plan B® emergency contraception available over-the-counter.

Emergency contraception is a safe and easy-to-use contraceptive that contains the same hormones commonly found in most birth control pills. It prevents pregnancy prior to fertilization, primarily by inhibiting ovulation, and secondarily by impairing the migration and function of sperm. It is most effective when used within twenty-four hours of unprotected intercourse, although it has been shown to prevent pregnancy for up to three days.

In December 2003, the Reproductive Health Advisory subcommittee recommended approval of emergency contraception for over-the-counter use. Studies conducted by Barr Laboratories, manufacturer of Plan B® emergency contraception, found that women do not substitute emergency contraception for other forms of birth control, they understand the drug labeling, and are not less likely to obtain other health services.

Increasing the availability of emergency contraception could reduce the rate of unintended pregnancies. Currently, half of all pregnancies in the United States (about 3 million) are unintended, and half of these pregnancies end in abortion. Widespread availability of emergency contraception could prevent over one million of these unplanned pregnancies a year.

Thank you for your continued support of women's reproductive health. I urge you to approve over-the-counter access to emergency contraception.

Sincerely,

Erin E. Tracy, M.D., M.P.H.

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